

SEP - 6 2001

K010431

REVISED COPY

**Lead-Lok Reusable Neurostimulation Electrodes
510(k) Summary**

The following information is submitted in accordance with the requirements of 21 CFR 807.92

Submitter's name: Chris Healy
Lead-Lok, Inc.
500 Airport Way
Sandpoint, Idaho 83864
Phone: 208-263-5071
FAX: 208-263-9654
Email Address: leadlok@micron.net

Contact person: Chris Healy

Date Prepared: 7 February 2001

Device Name: Lead-Lok Reusable Neurostimulation Electrodes

Common/Usual Name: Neurostimulation Electrodes

Classification Name: Electrodes, cutaneous

Predicate devices: K963125 (M & R Manufacturing, Inc.)
K932849 (Pepin Mfg., Inc.)

Device Description: Lead-Lok Reusable Neurostimulation Electrodes are non-sterile, disposable laminated, flexible structures composed of materials commonly used in this application:

First Layer – Various cloths, tapes, etc. including Tricot/polyester fabric, polyethylene foam or a polypropylene substrate, coated with biocompatible adhesive.

Second Layer – Various electrical conductors, i.e., conductive rubber or carbon coated with or without Ag/AgCl.

Third Layer – Biocompatible conductive hydrogel coupling media (AmGel 700 Series gels and Katecho KM 10 Series gels).

REVISED COPY

The electrodes are designed for single-patient/multiple application use. They have a low profile construction designed for comfort under clothing and utilize tan-tone fabric for reduced visibility. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin. The electrodes have three different types of contact points that can be used to link the stimulation device to the electrodes. These contact points are compatible with all standard, marketed Neurostimulation devices.

1. Pin style connection design - .080 in. diameter, female connection (hole in conductive rubber strip).
2. Lead wire assembly - 6" wire with .080 in. diameter female socket connected to one side of the wire.
3. Male snap assembly – Two-part sensor and stud mated together.

Technological Characteristics: Lead-Lok Reusable Neurostimulation electrodes are technologically equivalent to the predicate devices. They are physically and technically similar to those currently being marketed for "Neurostimulation" i.e., TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Safety and Effectiveness: Lead-Lok considers their Neurostimulation electrodes to be as safe and effective as the M&R Disposable Neurostimulation electrodes and PMI Neurostimulation electrodes which were previously found to be substantially equivalent via 510(k) Premarket Notifications. The safety issues analyzed were skin irritation. The effectiveness of the electrodes was determined by comparing impedance levels point to point testing using a volt meter.

The first safety issue considered was whether the gel, which is used to adhere the electrode to the skin and which is the only portion of the electrode to maintain skin contact, would cause any skin irritation. **The AmGel 700 Series gels (file number K983741) and the Katecho KM 10 Series of gels (file number K000870)**, either or both of which may be used in this family of electrodes, have passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization, and Primary Skin Irritation Tests.

REVISED COPY

Because there are no published performance standards for Neurostimulation electrodes, Lead-Lok uses impedance levels as the criteria for effectiveness testing. When measuring the electrodes' impedance, driven at 1K-Hz, using a standard voltmeter, the point-to-point impedance testing for all manufacturers' electrodes (including Lead-Lok) ranged from 125 – 250 ohms from the top center portion of the electrode to the underside of the outside edge. Once this testing was complete, it was determined that Lead-Lok's electrode impedance values were comparable to other marketed electrodes tested.

For the above reasons, Lead-Lok considers its Reusable TENS / NMES electrodes to be as safe and effective as the predicate devices, as well as to multiple other TENS/NMES electrodes currently being marketed including those manufactured by: Uni-Patch (K962910), Katecho, Incorporated (K000870), MSB Limited (K980229), Axelgaard (K983741), Selective Med Components, Inc. (K946230), Medtronic, Inc. (K875284), Medical Design & Manufacturing Corp. (K895604), and Labeltape Meditect, Inc. (K900656, K902719 and K894043).



SEP - 6 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Chris Healy
Vice President/General Manager
Lead-Lok, Incorporated
500 Airport Way
Sandpoint, Idaho 83864

Re: K010431

Trade/Device Name: Lead-Lok Reusable Neurostimulation Electrodes
Regulation Number: 882.1320, 882.1275
Regulation Name: Cutaneous Electrodes
Electroconductive media

Regulatory Class: Class II
Product Code: GXY, GYB
Dated: June 1, 2001
Received: June 8, 2001

Dear Mr. Healy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Chris Healy

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

REVISED COPY

510(k) NUMBER: K010431

DEVICE NAME: LEAD-LOK REUSABLE NEUROSTIMULATION
ELECTRODES

INDICATIONS FOR USE:

Lead-Lok Reusable Cutaneous Neurostimulation Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Lead-Lok Reusable Neurostimulation Electrodes are designed and intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation).


These electrodes will include the precaution statement: Federal Law restricts the device to sale by or on the order of a licensed practitioner or therapist.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR:

Over-the Counter-Use _____
(Optional Format 1-2-96)


(Division Sign-Off)
Division of General Restorative
and Neurological Devices

Page 6
Revised June 1, 2001

510(k) Number K010431 / S1